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DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
SOUTHWEST REGION

Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982
TELEPHONE: 214-655-8100

December 23, 1996

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Facility ID #165191
Central File # 1723046

WARNING LETTER

Mr. Dennis Long
Radiology Administrator
Ashley Valley Medical Center
151 West 200 North
Vernal, Utah 84078

Dear Mr. Long:

Your facility was inspected on October 30, 1996 by a representative from the State of Utah, Division of Radiation Control under contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

> 21 CFR 900.12(a)(1)(ii)(A) & (B): The interpreting physician is unqualified to interpret mammograms due to the lack of board certification from any of the approved boards or two months full-time training in the interpretation of mammograms: [redacted] M.D.

The specific deficiencies noted above appeared under the level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. These deficiencies may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliances that were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliances are:

> 21 CFR 900.12(1)(ii)(C): The interpreting physician does not have the initial training of 40 hours of continuing medical education in mammography: [redacted]

21 CFR 900.12(a)(1)(iii)(A): The interpreting physician's initial experience was inadequate (reading and interpreting mammograms from the examinations of at least 240 patients in six months): [redacted]

21 CFR 900.12(a)(1)(iv)(A): The interpreting physician did not meet the continuing experience requirement, i.e., interpreting an average of 40 patient examinations per month over a 24 month period following the date of the completion of the initial requirement.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions. Please be aware that your facility also had a Level 1 violation pertaining to personnel deficiencies during your last inspection, dated November 8, 1995. That inspection resulted in a Warning Letter to your facility.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- **impose civil money penalties** on a facility of up to $10,000 **for each failure** to substantially comply with, **or each day** of failure to substantially comply with, the Standards.
- **suspend or revoke a facility's FDA certificate** for failure to comply with the Standards.
- **seek an injunction in federal court** to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to **correct** all of the violations noted in this letter;
- each step your facility is taking to **prevent the recurrence** of similar violations. You should develop a mechanism that will continually check personnel requirements. Please provide a detailed explanation in your response to this office of any procedure that you put into place to rectify this deficiency in your program.

If your facility is unable to complete the corrective action within 15 working days, you should state

the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to B. Belinda Collins, Regional Radiological Health Representative, Food and Drug Administration, 7920 Elmbrook Drive, Suite 102, Dallas, Texas 75247-4982. Also, send a copy to the State radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Ms. Collins at 214-655-8100, extension 148.

Sincerely yours,

Edward R. Esparza
Regional Food and Drug Administration

enclosure: Federal Register, December 21, 1993

cc:
HFA-224
HFC-230
HFC-240
HFI-35 (redacted copy for public display)
HFZ-240
HFZ-322

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